

REMARKS

Claims 1-8, 10-14, 16-27, and 29-34 are pending and stand rejected. Claims 29-31 are withdrawn from consideration. Applicants respectfully request reconsideration of the present application in view of the above amendments and following remarks.

Applicants respectfully request that the claims as amended be entered for examination pursuant to MPEP §§ 714.12-13. Applicants submit that these amendments could not have been presented earlier because they address issues raised by the Examiner for the first time in the instant Office Action. Applicants consider that in view of these amendments and the arguments set forth below, the application is in condition for allowance. In the alternative, if the claims are not found to be in condition for allowance, the amendments would place the claims in better condition for appeal.

Amendments to the Claims

Applicants amend independent claims 1 and 19 to recite that the nonwoven polymeric material has a density greater than about 120 mg/cc. Support for these amendments can be found throughout the specification, for example, at Par. 0048 of the published application. Claim 34 is cancelled. No new matter is added.

Rejections Pursuant to 35 U.S.C. §112

Claims 1-8, 10-14, 16-27, and 32-34 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite. In particular, the Examiner asserts that “the metes and bounds of the term ‘high density’ are unclear. Applicants amend claims 1 and 19 to recite that the nonwoven polymeric material has a density greater than about 120 mg/cc, thereby obviating the basis for the Examiner’s rejection.

Rejections Pursuant to 35 U.S.C. §103

Claims 1-8, 10-14, 16-27, and 32-34 are rejected pursuant to 35 U.S.C. §103(a) as being unpatentable over U.S. Patent Publication No. US 2002/0127265 of Bowman et al. (“Bowman”), in view of WO 01/85226 of Huckle et al. (“Huckle”), and exemplified by

Boland et. al., (*J. Macromol. Sci.-Pure Appl. Chem.*, 2001, A38(12), p 1231-1243)
("Boland"). Applicants respectfully disagree with the Examiner's rejection.

Claims 1 and 19 each recite, in part, that the scaffold includes a "nonwoven polymeric material having a density greater than about 120 mg/cc." The Examiner relies on Bowman to teach the claimed nonwoven polymeric material, relying on Huckle only to teach *dry laid* nonwoven materials. However, Bowman does not teach or suggest a nonwoven material that has the claimed density. The Examiner asserts that because both Bowman and Applicants disclose VICRYL as an exemplary polymer, the "densities of the materials will be the same or nearly the same." This is incorrect. VICRYL is not a "nonwoven polymer." VYCRIL is merely the tradename of a 90/10 copolymer of PGA/PLA that can be used to make nonwoven materials. The mere fact that the same polymer can be used to form the reinforcing mesh of Bowman and Applicants' nonwoven polymeric material does not provide any indication that the density of the prior art reinforcing mesh and Applicants' nonwoven will be the same or even similar. The Examiner states that the instant application "defines some exemplary scaffolds as VICRYL (a copolymer of polyglycolic acid (PGA) and polylactic acid (PLA)) having a density of 236.6 mg/cc and PDS (polydioxanone) having a density of 275.5 mg/cc." However, the exemplary densities disclosed by Applicants are the densities of the nonwoven materials themselves, not the density of the polymer used to form the nonwoven materials. Although the polymer used to form the reinforcing mesh of Bowman and Applicants' nonwoven material can be the same, the density of the resulting materials are entirely different. Accordingly, Bowman fails to teach or suggest a nonwoven polymeric material having a density greater than about 120 mg/cc as required by claim 1.

Claim 1 also recites that "the scaffold has an initial modulus of elasticity greater than about 1.5 MPa." Bowman does not teach or suggest a scaffold having the claimed modulus of elasticity. Indeed, in the previous Office Action dated May 4, 2007, the Examiner admitted that Bowman "does not explicitly teach the specific modulus of elasticity...of the claimed scaffold." Although the Examiner has previously articulated arguments suggesting that the claimed properties are inherent, the Examiner has failed to provide the required rationale or evidence tending to show that the claimed properties would have been inherent in Bowman's scaffold. *See* MPEP 2112. Bowman discloses a foam implant reinforced by a mesh. Bowman discloses that the mesh reinforcing material is preferably a "low density, or

open knitted mesh material.” The reinforcing mesh disclosed by Bowman represents an entirely different composition from the dry laid nonwoven polymeric material of the present invention. The Examiner has not provided any basis in fact or technical reasoning to reasonably support the determination that the claimed material properties necessarily flow from the teachings of Bowman. There is simply no reason to believe that an implant reinforced by a low density mesh, as disclosed by Bowman, would have the claimed material properties, particularly the claimed modulus of elasticity.

Furthermore, the Examiner’s reliance on the Boland reference to support his arguments of inherency is improper. Boland teaches that the concentrations of polymers in an electrospinning solution affect the modulus of elasticity of the final electrospun material. However, Boland cannot provide the required basis in fact or technical reasoning to support a finding of inherency because the Boland reference relates to the material properties of electrospun materials, not the knitted mesh material disclosed by Bowman, or Applicants’ claimed dry laid nonwoven materials. Although Boland’s Chart 3 shows variations in elastic modulus for various concentrations of PGA in an electrospinning solution, the data is only relevant for nonwoven materials produced by an electrospinning process. The disclosure of Boland therefore has no bearing on the inherency of the claimed modulus of elasticity.

Accordingly, claims 1 and 19 distinguish over the combination of Bowman and Huckle and represent allowable subject matter. Claim 34 is cancelled, thereby obviating the Examiners rejection. Claims 2-8, 10-14, 16-18, 20-27, and 32-33, which depend from claims 1 and 19, distinguish over the cited art at least because they depend from an allowable base claim.

Obviousness-Type Double Patenting Rejections

The Examiner has provisionally rejected claims 1-8, 10-14, 16-27, and 32-33 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14, 17-29, and 32 of co-pending Application No. 11/427,477.

Applicants believe that all pending claims are allowable. As the instant application was filed earlier than the application that forms the basis of the non-statutory double patenting rejection, the Examiner should withdraw the provisional rejection and permit this application to issue as a patent without a terminal disclaimer (MPEP §804).

Conclusion

Applicants submit that all pending claims are allowable, and allowance thereof is respectfully requested. The Examiner is encouraged to telephone the undersigned attorney for Applicants if such communication is deemed necessary to expedite prosecution of this application.

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Respectfully submitted,

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